American College of Surgeons

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April 10, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: FDA's Draft Guidance Documents, "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme" and "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals;" **Docket No. 00D-0053**

Dear Sir or Madam:

On behalf of the over 62,000 Fellows of the American College of Surgeons, I am pleased to submit the following comments regarding the Food and Drug Administration's (FDA's) draft guidance documents, "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme," and "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals." These comments were developed in consultation with our Board of Governors' Committee on Surgical Practice in Hospitals and the Committee on Operating Room Environment.

The College would like to applaud the FDA for excluding "open-but-unused" single use devices (SUDs) and "permanently implanted pacemakers" from the proposed regulatory scheme, and to commend the FDA on the categorization system it has established. Both flowcharts for infection risk and inadequate performance risk are reasonable and easy to navigate. We would, however, like to comment on a few areas we believe the FDA should address.

First, we would like to suggest that FDA give some consideration to the relative risks associated with the various procedures in which these devices are used. This sort of risk is quite different from the nature of those that may be posed by infection or performance. For example, operating a reprocessed drill bit in the vicinity of the optic nerve is completely unlike using it in a bone flap.

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Also, we find that item four on the infection risk flowchart somewhat problematic for critical devices. This item states, "... it is evident that cleaning and sterilization/disinfection can be accomplished with the reprocessed SUD by using techniques directed by labeling for the reusable device." Usually, the SUD is manufactured by a different original equipment manufacturer (OEM) than the "equivalent" reusable device. Rarely, if ever, will the two devices be identical. Does the agency intend to hold the OEM of the reusable device responsible for the standards of sterilizing the SUD?

Further, the College is concerned about the liability implications of the question posed in the items labeled 2(b) and 5 of the inadequate performance risk flowchart: "Can visual inspection determine if performance has been affected?" The FDA goes on to say that "visual, critical failure of the device *may* be self-evident before or *during* use." We urge you to modify this language to eliminate any implication that the individual using the device is responsible for its performance. We are concerned that a reference to the *use* of the device infers that the surgeon or practitioner can easily identify a malfunctioning piece of equipment. What sort of visual inspection does the FDA expect a device user to conduct in an effort to determine if performance has been affected? Is an unaided visual inspection sufficient? Is the use of magnification expected, and, if so, how much?

We found it difficult to analyze the list of frequently reprocessed SUDs because no information was provided to show how the classifications were actually made. In other words, the list represents the results of the two flowcharts, but does not indicate how the devices were ranked by each. Consequently, it is difficult to determine the reason for some listings that, on the surface, seem anomalous. For example, it seems odd that the OB-GYN section lists a laparoscopic dissector as a low risk device, while a laparoscopic grasper is classified as high risk. Again, we can not tell how these risks were actually determined; they are nearly identical instruments and one might expect them to be classified identically. Similarly, why are endoscopic staplers rated low risk in the Gastroenterology section, but moderate risk in the Surgery section?

Furthermore, as recommended previously, the College believes that orthodontic metal or plastic braces should not be classified as reusable devices except in the case of the same patient wearing a device for a considerable length of time. In addition, we believe that endotracheal tubes and non-glass syringes should not be classified as reusable devices.

In the enforcement document, the FDA notes that "if any device designated by the companion Risk Scheme guidance as moderate or high risk is currently exempt from premarket requirements, FDA will propose to amend its classification regulations for those devices to require premarket submissions." The College is concerned that these future device classifications will not include some method of appeals process or inclusion of expert counsel, guidance, or direction.

The College continues to have some concerns regarding the FDA's list of definitions. Although generally appropriate, we still wonder whose standards will be used as the basis for determining such things as: what devices are, in fact, single-use devices; what is the proper reprocessing method; and what is the gold standard for resterilization? Further, as noted in our previous comments, with regard to the definition for "single-use" the College recommends that manufacturers who request this label distinction be required to demonstrate through scientific studies the reasons why their product cannot be used safely again with reprocessing.

In conclusion, we would like to emphasize that the viability of reprocessed devices and the benefits and detriments to patient care associated with their reuse are crucial issues that must be carefully assessed. Surgeons–often unaware of the reuse status of the sterilized instruments in a surgical tray–must accept on faith that the hospital has taken the necessary precautions to prepare the operating room and its equipment for providing safe and high-quality surgical care. Thus, in reviewing the draft documents, we were generally pleased to note that the FDA is striving to ensure both the quality and the safety of patient care.

Sincerely,

Thomas R. Russell, MD, FACS
Executive Director

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